

REMARKS

I. PRELIMINARY REMARKS

Claims 39, 41-43, 45-55, 57 and 59-62 have been amended. Claims 63-71 have been added. Claim 56 has been canceled. Claims 1, 3, 4, 6-16, 18-28, 33, 36, 37, 39, 41-55 and 57-71 remain in the application. Reexamination and reconsideration of the application, as amended, are respectfully requested.

Applicant notes with appreciation that claims 1, 3, 4, 6-16, 18-28, 33, 36, 37 and 49 have been allowed.

II. FORMALISTIC REJECTIONS

Claims 39, 41-48 and 50-62 have been rejected under 35 U.S.C. § 101 for being directed to non-statutory subject matter. Claims 39, 41-48 and 50-62 have also been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant respectfully submits that the rejections under 35 U.S.C. §§ 101 and 112, second paragraph, have been obviated by the amendments to the claims and should be withdrawn. Specifically, the phrase "that causes tissue to be heated" has been eliminated from independent claims 39 and 54. With respect to independent claim 50, the above-quoted phrase was (and is) not present and it appears that the inclusion of claims 50-53 in the rejections was a typographical error. The rejections under 35 U.S.C. §§ 101 and 112 should, therefore, be withdrawn.

III. REJECTIONS BASED ON THE SAAB/CAMPBELL/BURTON COMBINATION

A. The Rejections

Claims 39, 41-43 and 54-57 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of U.S. Patent No. 5,624,392 to Saab (“the Saab ‘392 patent”), U.S. Patent No. 5,409,483 to Campbell (“the Campbell ‘483 patent”) and/or U.S. Patent No. 5,496,271 to Burton (“the Burton ‘271 patent”). Claims 44 and 58 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Saab ‘392 patent, the Campbell ‘483 patent, the Burton ‘271 patent, and U.S. Patent No. 5,255,678 to Deslauriers (“the Deslauriers ‘678 patent”). Claims 46-48 and 60-62 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Saab ‘392 patent, the Campbell ‘483 patent, the Burton ‘271 patent, and U.S. Patent No. 5,403,311 to Abele (“the Abele ‘311 patent”).

As claim 56 has been canceled, applicant respectfully submits that the rejection thereof has been rendered moot. The rejections of the remaining claims under 35 U.S.C. § 103 are respectfully traversed with respect to the claims as amended above. Reconsideration thereof is respectfully requested.

B. Discussion Concerning Claims 39 and 41-43

Independent claim 39 calls for a combination of elements comprising “a surgical probe including a relatively short shaft ... an inflatable therapeutic element associated with the distal portion of the shaft, defining an internal fluid storage volume and having at least a portion thereof formed from a ***porous material that permits ionic transfer when the pores are filled with electrically conductive fluid***, an electrode located within the internal fluid storage volume, an infusion lumen ... and a ventilation lumen” and “an electrically conductive cooling fluid source ... adapted to ... ***continuously infuse electrically conductive cooling fluid*** to the internal fluid storage volume ... and draw cooling fluid from the internal fluid storage volume ... during a tissue heating

procedure." The combinations defined by claims 41-43 include, *inter alia*, the elements recited in claim 39. The cited references fail to teach or suggest such combinations.

The Saab '392 patent is directed to a heat transfer catheter that may be used to heat or cool tissue by supplying heat transfer fluids to internal body sites. [Column 1, lines 17-22.] The catheter illustrated in Figure 3 of the Saab '392 patent includes a balloon segment 72 that is connected to an inlet lumen 64 and an outlet lumen 68. Heat transfer fluid that is above, below, or the same temperature as normal body temperature (column 9, lines 42-44) passes through the inlet and outlet lumens 64 and 68 on its way to and from the balloon segment 72. The catheter may also include a tube 74 within lumen 64. The Saab '392 patent indicates that the tube 74 may comprise a catheter carrying "microwave antennas, lasers, ultrasound probes, induction coils, and electric heating elements." [Column 12, lines 38-47.] In contrast to the claimed combinations, however, nothing in the Saab '392 patent indicates that any portion of the balloon segment 72 is formed from "porous material that permits ionic transfer when the pores are filled with electrically conductive fluid." Nor is there any indication that the cooling fluid supplied to the balloon segment 72 (i.e. water or normal saline) is "electrically conductive."¹

The Campbell '483 and Burton '271 patents fail to remedy the aforementioned deficiencies in the Saab '392 patent. For example, the probes disclosed in the Campbell '483 patent transmit light energy through a transparent balloon to ablate tissue. The Burton '271 patent primarily discusses the use of microwave energy to heat tissue. Although it briefly mentions the use of radio frequency energy, there is nothing in the Burton '271 patent that would have even remotely suggest modifications to the Saab

¹ Applicant respectfully submits that, as used in the present application, "electrically conductive" fluid is fluid that has relatively low resistivity (e.g. about 5 ohm-cm) in order to reduce ohmic losses and ohmic heating. [See page 11, lines 18-29 of the specification.] Normal saline has a resistivity of about 50 ohm-cm and the resistivity of water with some ionizable impurities is orders of magnitude higher. Pure water is an insulator. Thus, although normal saline and water with some ionizable impurities will carry some electrical current, they are not "electrically conductive" as this term is used in the present application. To the extent that the Examiner disagrees with this analysis, applicant notes that the phrase "electrically conductive" has been further defined in newly presented dependent claims 64, 65, 67, 68, 70 and 71.

catheter which would have resulted in the Saab balloon segment 72 being formed from "porous material that permits ionic transfer when the pores are filled with electrically conductive fluid" or the use of "electrically conductive" cooling fluid.

As the Saab '392, Campbell '483 and Burton '271 patents fail to teach or suggest the combination of elements recited in independent claim 39, whether viewed alone or in combination, applicant respectfully submits that the rejection of claims 39 and 41-43 under 35 U.S.C. § 103 should be withdrawn.

C. Discussion Concerning Claims 44 and 46-48

Applicant respectfully submits that the Deslauriers '678 and Abele '311 patents fail to remedy the above-identified deficiencies in the Saab '392, Campbell '483 and Burton '271 patents with respect to independent claim 39, that claims 44 and 46-48 are patentable for at least the same reasons as independent claim 39, and that the rejections of claims 44 and 46-48 under 35 U.S.C. § 103 should also be withdrawn.

D. Discussion Concerning Claims 54, 55 and 57

Independent claim 54 calls for a combination of elements comprising "a surgical probe including a relatively short shaft ... and an **inflatable lesion formation element** associated with the distal portion of the shaft and adapted to form lesions in tissue" and "an electrically conductive cooling fluid source operably connected to the inflatable lesion formation element and adapted to ... **continuously infuse and ventilate electrically conductive cooling fluid** to and from a volume within the inflatable lesion formation element during a lesion formation procedure." The combinations defined by claims 55 and 57 include, *inter alia*, the elements recited in claim 54. The cited references fail to teach or suggest such combinations.

The Saab '392 patent is directed to a heat transfer catheter that may be used to heat or cool tissue by supplying heat transfer fluids to internal body sites. The Saab '392

patent does not, however, teach or suggest the combination of “an inflatable lesion formation element” and “an electrically conductive cooling fluid source operably connected to the inflatable lesion formation element and adapted to ... continuously infuse and ventilate electrically conductive cooling fluid.” For example, even assuming for the sake of argument that the aforementioned balloon segment 72 is an “inflatable lesion formation element,” there is nothing in the Saab ‘392 patent which suggests that the cooling fluid disclosed therein (i.e. water or normal saline) is “electrically conductive,” as this term is used in the present application. Given that the tissue is being heated by the “microwave antennas, lasers, ultrasound probes, induction coils, and electric heating elements,” there is no reason to use “electrically conductive” cooling fluid. [It is also noteworthy that there is no indication that that the balloon segment 72 electrically conductive or otherwise capable of allowing current to pass therethrough.]

The Campbell ‘483 and Burton ‘271 patents fail to remedy the aforementioned deficiencies in the Saab ‘392 patent. For example, the probes disclosed in the Campbell ‘483 patent transmit light energy through a transparent balloon to ablate tissue and would not have suggested using “electrically conductive” cooling fluid. The Burton ‘271 patent primarily discusses the use of microwave energy to heat tissue. Although it briefly mentions the use of radio frequency energy, there is nothing in the Burton ‘271 patent which indicates that the radio frequency energy embodiment would have employed “electrically conductive” cooling fluid.

As the Saab ‘392, Campbell ‘483 and Burton ‘271 patents fail to teach or suggest the combination of elements recited in independent claim 54, whether viewed alone or in combination, applicant respectfully submits that the rejection of claims 54, 55 and 57 under 35 U.S.C. § 103 should be withdrawn.

E. Discussion Concerning Claims 58 and 60-62

Applicant respectfully submits that the Deslauriers ‘678 and Abele ‘311 patents fail to remedy the above-identified deficiencies in the Saab ‘392, Campbell ‘483 and Burton ‘271 patents with respect to independent claim 54, that claims 58 and 60-62 are

patentable for at least the same reasons as independent claim 54, and that the rejections of claims 58 and 60-62 under 35 U.S.C. § 103 should also be withdrawn.

IV. REJECTIONS BASED ON THE STERN/SAAB COMBINATION

A. The Rejections

Claims 39, 41-43, 50, 53 and 54-57 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of U.S. Patent No. 5,443,470 to Stern ("the Stern '470 patent") and the Saab '392 patent. Claims 44, 51, 52 and 58 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Stern '470 patent, the Saab '392 patent and the Deslauriers '678 patent. Claims 46-48 and 60-62 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Stern '470 patent, the Saab '392 patent and the Abele '311 patent. Claims 45 and 59 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Stern '470 patent, the Saab '392 patent and U.S. Patent No. 5,047,028 to Qian ("the Qian '028 patent").

As claim 56 has been canceled, applicant respectfully submits that the rejection thereof has been rendered moot. The rejections of the remaining claims under 35 U.S.C. § 103 are respectfully traversed with respect to the claims as amended above. Reconsideration thereof is respectfully requested.

B. Discussion Concerning Claims 39 and 41-43

Independent claim 39 calls for a combination of elements comprising "a surgical probe including a relatively short shaft ... an inflatable therapeutic element associated with the distal portion of the shaft, defining an internal fluid storage volume and having at least a portion thereof formed from a **porous material that permits ionic transfer when the pores are filled with electrically conductive fluid**, an electrode located within the internal fluid storage volume, an infusion lumen ... and a ventilation lumen"

and “an electrically conductive cooling fluid source ... adapted to ... **continuously infuse electrically conductive cooling fluid** to the internal fluid storage volume ... and draw cooling fluid from the internal fluid storage volume ... during a tissue heating procedure.” The combinations defined by claims 41-43 include, *inter alia*, the elements recited in claim 39. The cited references fail to teach or suggest such combinations.

As illustrated in Figures 1-3, the Stern '470 patent discloses an ablation device that includes an inflatable balloon 14 with a conductive **outer** surface 35 that is used to heat tissue. The Stern '470 patent also discloses ablation devices with individually controllable electrode segments on the **outer** surface of an inflatable balloon. [See Figures 4a and 4b.] In contrast to the invention defined by independent claim 39, the Stern '470 patent does not disclose “an inflatable therapeutic element ... having at least a portion thereof formed from a porous material that permits ionic transfer when the pores are filled with electrically conductive fluid” and “an electrically conductive cooling fluid source.”

Applicant respectfully submits that the Saab '392 patent fails to remedy this deficiency in the Stern '470 patent. For example, the Saab '392 patent does not teach or suggest “an inflatable therapeutic element ... having at least a portion thereof formed from a porous material that permits ionic transfer when the pores are filled with electrically conductive fluid.” The Saab '392 patent also fails to teach or suggest the use of “electrically conductive” cooling fluid and, instead, specifically calls for the use of non-conductive fluid. [Column 4, lines 47-53.] Moreover, given the design of the Stern ablation devices, there is simply no reason to supply “electrically conductive” cooling fluid to the Stern ablation devices.

As the Stern '470 and Saab '392 patents fail to teach or suggest the combination of elements recited in independent claim 39, whether viewed alone or in combination, applicant respectfully submits that the rejection of claims 39 and 41-43 under 35 U.S.C. § 103 should be withdrawn.

C. Discussion Concerning Claims 44-48

Applicant respectfully submits that the Deslauriers '678, Abele '311 and Qian '028 patents fail to remedy the above-identified deficiencies in the Stern '470 and Saab '392 patents with respect to independent claim 39, that claims 44-48 are patentable for at least the same reasons as independent claim 39, and that the rejections of claims 44-48 under 35 U.S.C. § 103 should also be withdrawn.

D. Discussion Concerning Claims 50 and 53

Independent claim 50 calls for a combination of elements comprising "a relatively short, relatively stiff shaft," "an electrode carried on the distal portion of the shaft," "means, associated with the distal portion of the shaft, for inflating and transmitting current from the electrode to tissue at a level sufficient to cause the formation of lesions without substantial liquid perfusion" and "means for continuously infusing and ventilating electrically conductive cooling fluid to and from a volume within the means for inflating and transmitting current." Claim 53 depends from claim 50 and includes, *inter alia*, the combination defined by claim 50.

The Stern '470 patent discloses an ablation device that includes an inflatable balloon with a conductive outer surface (or individually controllable electrode segments on the outer surface) that is used to heat tissue. Thus, in contrast to the invention defined by independent claim 50, the Stern '470 patent does not teach or suggest "means ... for inflating and transmitting current from the electrode [on a shaft] to tissue at a level sufficient to cause the formation of lesions without substantial liquid perfusion." The Stern '470 patent also fails to teach or suggest "means for continuously infusing and ventilating electrically conductive cooling fluid to and from a volume within [a] means for inflating and transmitting current." In fact, the Stern '470 patent specifically calls for non-conductive fluid.

The Saab '392 patent fails to remedy the deficiencies in the Stern '470 patent. More specifically, the fluid disclosed in the Saab '392 patent is not "electrically conductive"

and there is simply no reason to supply “electrically conductive” cooling fluid to the interior of the conductive **outer** surface ablation devices disclosed in the Stern ‘470 patent.

As the Stern ‘470 and Saab ‘392 patents fail to teach or suggest the combination of elements recited in independent claim 50, applicant respectfully submits that claims 50 and 53 are patentable thereover and that the rejection under 35 U.S.C. § 103 should be withdrawn.

E. Discussion Concerning Claims 51 and 52

Applicant respectfully submits that the Deslauriers ‘678 patent fails to remedy the above-identified deficiencies in the Stern ‘470 patent, that claims 51 and 52 are patentable for at least the same reasons as independent claim 50, and that the rejection of claims 51 and 52 under 35 U.S.C. § 103 should be withdrawn.

F. Discussion Concerning Claims 54, 55 and 57

Independent claim 54 calls for a combination of elements comprising “a surgical probe including a relatively short shaft ... and an **inflatable lesion formation element** associated with the distal portion of the shaft and adapted to form lesions in tissue” and “an electrically conductive cooling fluid source operably connected to the inflatable lesion formation element and adapted to ... **continuously infuse and ventilate electrically conductive cooling fluid** to and from a volume within the inflatable lesion formation element during a lesion formation procedure.” The combinations defined by claims 55 and 57 include, *inter alia*, the elements recited in claim 54. The cited references fail to teach or suggest such combinations.

For example, and as noted above, the Stern ‘470 patent specifically calls for the use of non-conductive fluid and the fluid disclosed in the Saab ‘392 patent (i.e. water or normal saline) is not “electrically conductive,” as this term is used in the present application. Moreover, in view of the fact that the Stern inflatable balloons have a conductive outer surface (or individually controllable electrode segments on the outer

surface), there is simply no reason to cool the Stern balloons with “electrically conductive” cooling fluid.

As the Stern ‘470 and Saab ‘392 patents fail to teach or suggest the combination of elements recited in independent claim 54, applicant respectfully submits that claims 54, 55 and 57 are patentable thereover and that the rejection under 35 U.S.C. § 103 should be withdrawn.

G. Discussion Concerning Claims 58-62

Applicant respectfully submits that the Deslauriers ‘678, Abele ‘311 and Qian ‘028 patents fail to remedy the above-identified deficiencies in the Stern ‘470 and Saab ‘392 patents with respect to independent claim 54, that claims 58-62 are patentable for at least the same reasons as independent claim 54, and that the rejections of claims 58-62 under 35 U.S.C. § 103 should also be withdrawn.

V. NEWLY PRESENTED CLAIMS 63-71

Newly presented claims 63-65 depend from independent claim 39 and are patentable for at least the same reasons as claim 39.

Newly presented claims 66-68 depend from independent claim 50 and are patentable for at least the same reasons as claim 50.

Newly presented claims 69-71 depend from independent claim 54 and are patentable for at least the same reasons as claim 54.

VI. CLOSING REMARKS

In view of the foregoing, it is respectfully submitted that the claims in the application are in condition for allowance. Reexamination and reconsideration of the application, as amended, are respectfully requested. Allowance of the claims at an early date is courteously solicited.

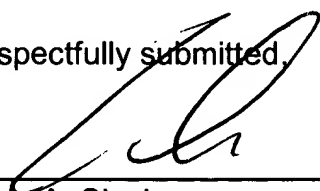
If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call applicant's undersigned representative at (310) 563-1458 to discuss the steps necessary for placing the application in condition for allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

8/6/04
Date

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Respectfully submitted,



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